

Briviact® (Brivaracetam 10mg/ml) Oral Solution: Bottles with narrow neck diameter

Dear Pharmacists,

UCB Pharma Ltd in agreement with the European Medicines Agency and the Medicines and Healthcare products Regulatory Agency would like to inform you of the following:

Summary

- **A small number of glass bottles from some batches of Briviact® 10mg/mL oral solution, 300 mL, have a slightly narrower neck diameter, making it difficult to insert the press-in bottle adapter (PIBA) to extract the solution with the oral syringe.**
- **Discuss this issue with the patient/caregiver when dispensing the product and, if possible, check with the patient/caregiver if the PIBA fits in the dispensed bottle. If the PIBA does not fit in the dispensed bottle and there are difficulties extracting the dose, a replacement bottle should be provided.**
- **The issue of narrow neck of the bottle does not impact the safety of the Briviact® oral solution itself. However, a minimal risk of dosing error due to the use of the defective bottle or to the use of the syringe without the PIBA, cannot be ruled out.**
- **UCB is working with glass bottle manufacturer to solve this issue. The potentially impacted batch numbers are provided below and per your country one or more of the batches may be applicable. There may be very few bottles affected in the distributed batches whose shelf-life is up to 2025. Therefore, complaints could be received until that timeline.**

Background information

Briviact® is indicated as adjunctive therapy in treatment of partial onset seizures with or without secondary generalisation in patients from 4 years of age with epilepsy.

A small number of glass bottles from following batches of Briviact® oral solution have a slightly narrower neck diameter, and the press-in bottle adapter (PIBA) included in the package therefore does not fit into these bottles. This makes it difficult to extract the dose of the oral solution from the bottle using the oral syringe (as described in the product information leaflet).

Potentially impacted batches include batch numbers outlined in the table below.

Product Name	Batch Number	Expiry date
Briviact 10 mg/ml oral solution	299914	30 Nov 2023
Briviact 10 mg/ml oral solution	306235	31 Mar 2024

There may be very few bottles affected in the distributed batches whose shelf-life is up to 2025. Therefore, complaints could be received until that timeline.

The patient/caregiver should be informed of this issue when dispensing Briviact® 10mg/mL oral solution. If possible, fitting of the PIBA in the dispensed bottled should be verified with the patient/caregiver.

If the PIBA does not fit in the dispensed bottle and there are difficulties extracting the dose, a replacement bottle should be provided. UCB will reimburse the cost of this replacement.

Although the dosing syringes included with the Briviact® oral solution are not impacted, minimal risk of dosing errors cannot be ruled out due to this issue. However, the issue of narrow neck of the bottle does not impact the safety of the Briviact® oral solution itself.

Call for reporting

Patient safety is of utmost importance to UCB. This allows continuous monitoring of the benefit-risk balance of the medicinal product.

Please refer to the product information leaflet to report any side effects with the product.

Please report any suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.

It is easiest and quickest to report ADRs online via the Yellow Card website: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store.

UCB contact information

Should you have any questions, please contact UCB Pharma Ltd Tel: 01753777100; Email: UCBcares.UK@ucb.com.

Yours sincerely,

Medical Solutions Lead

Michelle Whelton

